K062888

ELECTRIC MEDICAL GROUP

EMG TECHNOLOGY CO., LTD.
No.58, 35rd., Taichung Industrial Park,
Taiwan
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OCT 24 2006

" 510(k) SUMMARY "

Submitter's Name: ***EMG Technology Co., Ltd.***

No. 58, 35 Rd., Taichung Industrial Park, Shituen Chiu, 40768, Taiwan, ROC

Date summary prepared: September 23, 2006

Device Name:

Proprietary Name:	Middle Wheel Drive Power Chair, CWD01
Common or Usual Name:	Powered Wheelchair
Classification Name:	Powered Wheelchair, Class II, 21 CFR 890.3860

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a seated position.

Description of the device:

The Middle Wheel Drive Power Chair, CWD01 is an indoor / outdoor Powered Wheelchair that is battery operated. It has a base with four-wheeled with a seat. The movement of the Wheelchair is controlled by the rider who uses hand controls located at the top of the steering column. The device can be disassembled for transport and is provided with an onboard battery charger.

Performance Testing:

EMC Report ANSI / RESNA WC/Vol.2-1998, CISPR 11: 1990, EN61000-3-2: 1995, IEC61000-3-3: 1995 (Electrically Powered Wheelchairs, controller, and their chargers – requirements and test methods)

Legally marketed device for substantial equivalence comparison:

EPW POWERED WHEELCHAIR GP-201 (**K023148**)

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C.1 SUMMARY TABLE

ITEMS	SUBJECT DEVICE	PREDICATE DEVICE
BRAND NAME	*EMG, EPW*	*EMG, EPW*
MANUFACTURER	EMG Technology	EMG Technology
SERIES	Power wheels	Power wheels
MODEL NO	CWD01	GP-201
510K NO	TBA	**K023148**
INTENDED USE	SAME	*The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.*
Frame	SAME	**Unfoldable**
Overall dimension		
Overall length	90 cm / 35.4"	38"
Overall width	65 cm / 25.6"	24"
Overall height	113 cm / 44.5"	18" from seat
Weight limit	136 kgs / 300 lbs	350 lbs
Maximum speed	5 km/hr (3.2 mph)	5.0 mph
Electronics	Dynamic Shark controller	Dynamic DL controller
Batteries		
Quantity	Two	Two
Type	U1, 35Ah gel cell 12VDC	U1, 30Ah gel cell 12VDC
Range per charge	24 miles (40 km)	22 miles
Suspension	SAME	Cross brace

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ITEMS	SUBJECT DEVICE	PREDICATE DEVICE
Rear wheels	10" PU foaming tire	10" pneumatic
Casters	6" x 2" pneumatic	8" x 2" pneumatic
Footplates	SAME	Aluminum
Seat size **Width** **Depth** **Height**	SAME	Backrest Height 19-24" adjustable Depth 18"
Back angle adjustment	SAME	20 degree
Seat-to-floor height	SAME	18"
Incline	12 degree	6 degrees
Back upholstery	SAME	Fabric
Armrest types	SAME	Removable
Wheelchair Weight	83.5 kg, batteries includes	52.66 kg, batteries includes
Recharger	SAME	24 VDC (UL 1310 certified)
WHEEL LOCK	SAME	Switch to lock
Warranty **3 years** **1 year**	SAME	3 years: Main frame Controller / gear motor / main components w/o exhaustive and wear parts

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C.2 COMPARISON SUMMARY

(We place the related information for the predicate device in the following pages.)

We can know from the above table that the intended use between two devices is the same. The overall dimensions and visional appearance are similar. The **batteries** used are similar, i.e., U1 type. The **control** systems for the two devices are same supplier; it is Dynamic different controller types for the two devices. The **recharge** for the two devices are also used the same resource and the recharger is certified by UL 1310. The seat dimensions are same. Besides, the **back upholstery** is the same material, and also passed the resistance ignition test by SGS. The safety and performance functions of two systems are assured and validated. They are substantially equivalent.

The maximum cruising range is similar. This means the cruising range of the new device is 24 miles and 22 miles for the predicate device. This is mainly due to the fact that the batteries for the two devices are smaller. Certainly the real range depends on the practice environments, i.e., weight, surface, incline, and temperature. For the real life use, the two devices are substantially equivalent.

The maximum speed for the new device is 3.2 mph and 5.0 mph for the predicate device. Slower speed means the new device shall meet relevant requirements for the braking time, distance, and dynamic stability for safety considerations. The different maximum speeds do not lead any safety considerations and they are substantially equivalent in this aspect.

To sum up the mainly different of the two devices are only appearance dimensions, i.e., the frame, overall dimensions, and the size of wheels. For the regular operator, these differences for the two devices do not lead to any performance differences, and the three devices are substantially equivalent.

Based on the above the information and the analysis, we know that the subject device, the predicate device have the same intended use the same technological aspects and only minor dimensions and material differences exist. We believe that FDA can decide the subject device and the predicate device are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

EMG Technology Co., Ltd.
% Dr. Jen Ke-Min
ROC Chinese-European Industrial Research Society
No. 58, Fu-Chiun Street
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Taiwan, ROC

OCT 2 4 2006

Re: K062888
Trade/Device Name: Middle Wheel Drive Power, Chair CWD01
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: September 23, 2006
Received: September 26, 2006

Dear Dr. Ke-Min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (K) Number (If Known): K062888

Device Name: *Middle Wheel Drive Power Chair, CWD01*

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062888